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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,472	09/23/2003	Ray W. Wood	029318-0976	9063

22428 7590 10/11/2005

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/667,472

Applicant(s)

WOOD ET AL.

Examiner

Mina Haghighatian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-74 is/are pending in the application.
- 4a) Of the above claim(s) 29-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-22, 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 23 and 27-74 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/03 & 05/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 10-28 in the reply filed on 08/11/05 is acknowledged. The traversal is on the ground(s) that "search and examination of the claims of Groups I, II and III is not unduly burdensome". This is not found persuasive because as shown in the Restriction Requirements, the claims of Group I are classified in a different class and subclass than the other two Groups. It was also discussed that formulations of Group I can be made by other methods and is not restricted or dependent on the method of Groups II and III. The process steps of Groups II and III comprises various limitations that are not disclosed in formulations of Group I and thus requires different search and examination.

The requirement is still deemed proper and is therefore made FINAL.

NOTE: claims 23 and 27-28 include non-elected species and thus would not be examined at this time.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-22 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liversidge et al (5,145,684) in view of Drug Information Handbook.

Liversidge et al teach dispersible particles consisting essentially of a crystalline drug substance having a surface modifier adsorbed on the surface thereof in an amount sufficient to maintain an effective average particle size of less than about 400 nm (see abstract and col. 1, lines 32-43). Liversidge discloses that the liquid media can be aqueous salt solutions, safflower oil and solvents such as ethanol, t-butanol, hexane and glycol. Suitable drugs include corticosteroids, such as steroid A. The surface modifiers can be selected from the group including non-ionic and anionic surfactants such as polyvinylpyrrolidone (see cols. 3-4).

Liversidge also discloses that the effective average particle size of less than 400 nm, or less than 100 nm is preferred. Also at least 99% of the particles have a particle size less than the effective average, eg., 400 nm (see col. 5, lines 26-40).

Liversidge teaches that the surface modifier can be present in an amount of 0.

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1 to 90%, preferably 20-60% by weight based on the total weight of dry particles (col. 7, lines 15-20). Liversidge, while disclosing corticosteroids, such as steroid A as suitable active agents for nanoparticulate formulations, lacks specific disclosure of beclomethasone dipropionate.

Drug Information Handbook discloses beclomethasone dipropionate as a suitable active agent for formulations for delivery into lungs or nasal passages.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made, given the general formulations of Liversidge on formulations containing active agents including corticosteroids, to have looked in the art for other specific species of corticosteroids suitable for formation of compositions, as disclosed in Drug Information Handbook, with reasonable expectations of successfully preparing formulations comprising different active agents for treating different disorders.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-22, 24-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,264,922 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. In other words claims 10-22 and 24-26 are generic to all that is recited in claims 1-16 of U.S. Patent No. 6,264,922 B1. That is, claims 1-16 of U.S. Patent No. 6,264,922 B1 fall entirely within the scope of claims 10-22 and 24-26. Specifically, the liquid droplets of reference claims, with a particle size of less than 1000nm, or less than 400 nm or less than 100 nm, and the active agent of beclomethasone dipropionate of claims 8 and 16 are substantially the same as the nanoparticulate compositions comprising beclomethasone dipropionate of instant claims. Both sets of claims require surface modifiers, and other limitations which are the same.

Claims 10-22, 24-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,811,767 B. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. In other words claims 10-22 and 24-26 are generic to all that is recited in claims 1-13 of U.S. Patent No. 6,811,767 B1. That is, claims 1-13 of U.S. Patent No. 6,811,767 B1 fall entirely within the scope of claims 10-22 and 24-26. Specifically, the

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liquid droplets of reference claims, with a particle size of less than 1000 nm, or less than 400 nm or less than 100 nm, are substantially the same as the nanoparticulate compositions of instant claims. Both sets of claims require surface modifiers, and other limitations which are the same. The reference claims do not require beclomethasone dipropionate as active agent, however the specification discloses that beclomethasone dipropionate is a suitable active agent for nanoparticulate formulations.

Claims 10-22, 24-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5,747,001. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by the reference claims. In other words claims 10-22 and 24-26 are generic to all that is recited in claims of U.S. Patent No. 5,747,001. That is, claims of U.S. Patent No. 5,747,001 fall entirely within the scope of claims 10-22 and 24-26. Specifically, the liquid droplets of reference claims, with a particle size of less than 400 nm, and the active agent of beclomethasone dipropionate are substantially the same as the nanoparticulate compositions comprising beclomethasone dipropionate of instant claims. Both sets of claims require surface modifiers, and other limitations which are the same.

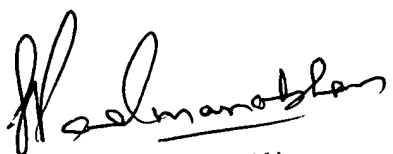
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mina Haghighatian
September 22, 2005



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER